

## PATENT COOPERATION TREATY



## PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY  
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference <b>C1-A0223P</b>	<b>FOR FURTHER ACTION</b>		See Form PCT/IPEA/416
International application No. <b>PCT/JP2004/010444</b>	International filing date (day/month/year) <b>15 July 2004 (15.07.2004)</b>	Priority date (day/month/year) <b>15 July 2003 (15.07.2003)</b>	
International Patent Classification (IPC) or national classification and IPC <b>C12N 15/13, 5/10, C12P 21/02, C07K 16/18, A61K 39/395, G01N 33/561, 33/53, 27/447</b>			
Applicant <b>CHUGAI SEIYAKU KABUSHIKI KAISHA</b>			

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

a.  (*sent to the applicant and to the International Bureau*) a total of \_\_\_\_\_ sheets, as follows:

- sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
- sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

b.  (*sent to the International Bureau only*) a total of (indicate type and number of electronic carrier(s)) Disc 1, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

- Box No. I Basis of the report
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

Date of submission of the demand <b>15 July 2004 (15.07.2004)</b>	Date of completion of this report <b>03 June 2005 (03.06.2005)</b>
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2004/010444

## Box No. 1 Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

This report is based on translations from the original language into the following language \_\_\_\_\_, which is language of a translation furnished for the purpose of:

- international search (under Rules 12.3 and 23.1(b))
- publication of the international application (under Rule 12.4)
- international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on (replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):

The international application as originally filed/furnished

the description:

pages \_\_\_\_\_, as originally filed/furnished

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

the claims:

pages \_\_\_\_\_, as originally filed/furnished

pages\* \_\_\_\_\_, as amended (together with any statement) under Article 19

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

the drawings:

pages \_\_\_\_\_, as originally filed/furnished

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

a sequence listing and/or any related table(s) -- see Supplemental Box Relating to Sequence Listing.

3.  The amendments have resulted in the cancellation of:

- the description, pages \_\_\_\_\_
- the claims, Nos. \_\_\_\_\_
- the drawings, sheets/figs \_\_\_\_\_
- the sequence listing (specify): \_\_\_\_\_
- any table(s) related to sequence listing (specify): \_\_\_\_\_

4.  This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- the description, pages \_\_\_\_\_
- the claims, Nos. \_\_\_\_\_
- the drawings, sheets/figs \_\_\_\_\_
- the sequence listing (specify): \_\_\_\_\_
- any table(s) related to sequence listing (specify): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2004/010444

## Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

the entire international application.

claims Nos. 9-65

because:

the said international application, or the said claims Nos. \_\_\_\_\_ relate to the following subject matter which does not require an international preliminary examination (specify):

the description, claims or drawings (*indicate particular elements below*) or said claims Nos. \_\_\_\_\_ are so unclear that no meaningful opinion could be formed (specify):

the claims, or said claims Nos. 9-65 are so inadequately supported by the description that no meaningful opinion could be formed.

no international search report has been established for said claims Nos. \_\_\_\_\_

the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form  has not been furnished does not comply with the standardthe computer readable form  has not been furnished does not comply with the standard

the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

see Supplemental Box for further details.

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2004/010444

**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement****Novelty (N)**Claims 1-8 YES

NO

Claims

YES

**Inventive step (IS)**

Claims

NO

Claims

YES

**Industrial applicability (IA)**

Claims

YES

Claims

NO

**2. Citations and explanations (Rule 70.7)**

Document 1: Nichidai Shigaku (2002), Vol.76, No.5, p.425-433

Document 2: Enzyme Microb Technol (1997), Vol.21, No.3, p.203-211

**Claims 1 through 8**

The inventions relating to claims 1 through 8 do not appear to involve an inventive step in view of document 1.

Document 1 describes antibody production cells that can produce 6.6 to 7.1mg/L of IgM antibodies by culturing mouse hybridoma cell line B cells. There is a discrepancy between the antibody production volume of the invention described in document 1 and that of the Claims 1, 3, 5 and 6 of this patent application.

Document 2 describes that a mouse hybridoma cell line *Zac3*, created by a fusion of a mouse myloma cell and lymphocyte cell, adjusts culture medium nutrient enhancement conditions and promotes expression such that it achieves a state in which 115 to 14,000mg/L or more of IgA from a state in which 14 to 42mg/L or more of IgA is generated.

A person skilled in the art could easily conceive of, with the aim of obtaining a large quantity of antibodies, attempting to produce the antibody-producing cells described in document 1 under the nutrient conditions described in document 2, and in so doing, this examination finds that the cells described in document 1 can also produce 100mg/L or more of IgM based on the description in document 2.

Also, because using a transforming cell, a prokaryotic cell and a CHO cell are ordinary means for producing antibodies, this examination finds that they are not particularly outstanding points.

Therefore, the inventions of claims 1 through 8, given the invention in document 1, are just inventions that could be appropriately achieved by a person skilled in the art.

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2004/010444

## Supplemental Box Relating to Sequence Listing

## Continuation of Box No. 1, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis that of:

## a. type of material

a sequence listing  
 table(s) related to the sequence listing

## b. format of material

in written format  
 in computer readable form

## c. time of filing/furnishing

contained in the international application as filed  
 filed together with the international application in computer readable form  
 furnished subsequently to this Authority for the purpose of search and/or examination  
 received by this Authority as an amendment\* on \_\_\_\_\_

2.  In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

3. Additional comments:

\* If item 4 in Box No. 1 applies, the listing and /or table(s) related thereto, which form part of the basis of the report, may be marked "superseded".